

What is claimed is:

1. An isolated nucleic acid molecule comprising an allelic variant of a polymorphic region of a 5-LO gene, wherein the allelic variant comprises one or more nucleotide sequences selected from the group consisting of those set forth in SEQ ID NO:4, SEQ ID NO:5, and SEQ ID NO:6, or the complement thereof.
2. The method of claim 1, wherein the allelic variant further comprises one or more nucleotide sequences selected from the group consisting of SEQ ID NO: 7 and SEQ ID NO:8, or the complement thereof.
3. The isolated nucleic acid molecule of claims 1 or 2, further comprising at least one variant Sp1 binding site, or the complement thereof.
4. An isolated nucleic acid molecule comprising a haplotype, wherein the haplotype comprises one or more of SEQ ID NO: 4, SEQ ID NO: 5, and SEQ ID NO: 6, one or more of SEQ ID NO: 7 and SEQ ID NO: 8, or the complements thereof, and wherein the nucleic acid molecule is a 5-LO gene.
5. An isolated nucleic acid molecule comprising the nucleotide sequence set forth in SEQ ID NO:1, or a portion thereof, wherein said nucleic acid molecule comprises one or more nucleotide residues selected from the group consisting of an adenine at residue 1000 of SEQ ID NO:1, deleted residues 472-477 of SEQ ID NO:1, and an adenine at residue 559 of SEQ ID NO:1, or the complements thereof.

6. The isolated nucleic acid molecule of claim 5, further comprising one or more nucleotide residues selected from the group consisting of an adenine at residue 84 of SEQ ID NO:1, and an adenine at residue 137 of SEQ ID NO:1, or the complements thereof.

5 7. The isolated nucleic acid molecule of claim 5, further at least one non-wild-type Sp1 binding site allele, or the complement thereof.

8. A kit comprising a probe or primer which is capable of hybridizing to the nucleic acid molecule of any of claims 1, 2, 4, 5, 6, or 7.

10

9. The kit of claim 8, wherein the probe or primer comprises a nucleotide sequence from about 15 to about 30 nucleotides.

10. The kit of claim 8, wherein the probe or primer comprises a nucleotide sequence selected from the group consisting of nucleic acids having a nucleotide sequence set forth in SEQ ID NOs: 9-60.

15

11. The kit of claim 8, wherein the probe or primer is labeled

20 12. A method for determining whether an asthma patient will be responsive to treatment with a 5-LO inhibitor, comprising

a) obtaining a nucleic acid sample from the asthma patient;  
b) determining the presence of an allelic variant which differs from the reference sequence set forth in SEQ ID NO:1; and

25

c) determining whether the asthma patient will be responsive to treatment with a 5-LO inhibitor based on the presence of an allelic variant which differs from the reference sequence set forth in SEQ ID NO:1, wherein the allelic variant comprises one or more nucleotide sequences selected from the group consisting of those set forth in SEQ ID NO: 4, SEQ ID NO:5, and SEQ ID NO:6, or the complement thereof.

30

10071441-000702

13. The method of claim 12, wherein the allelic variant further comprises one or more nucleotide sequences selected from the group consisting of SEQ ID NO: 7 and SEQ ID NO:8, or the complement thereof.

5 14. The method of claim 12 or 13, wherein the allelic variant further comprising at least one non-wild-type Sp1 binding site allele, or the complement thereof.

15. A method for determining whether an asthma patient has a more or less severe asthma phenotype, comprising

- 10 a) obtaining a nucleic acid sample from the asthma patient;
- b) determining the presence of an allelic variant which differs from the reference sequence set forth in SEQ ID NO:1; and
- c) determining whether the asthma patient has a more or less severe asthma phenotype based on the presence of an allelic variant which differs from the reference
- 15 sequence set forth in SEQ ID NO:1, wherein the allelic variant comprises one or more nucleotide sequences selected from the group consisting of those set forth in SEQ ID NO: 4, SEQ ID NO:5, and SEQ ID NO:6, or the complement thereof.

16. The method of claim 15, wherein the allelic variant further comprises one or more

20 nucleotide sequences selected from the group consisting of SEQ ID NO: 7 and SEQ ID NO:8, or the complement thereof.

17. The method of claim 15 or 16, wherein the allelic variant further comprising at least one non-wild-type Sp1 binding site allele, or the complement thereof.

25

18. A method for selecting the appropriate drug to administer to a patient who has asthma, comprising

- a) obtaining a nucleic acid sample from the patient;
- b) determining the presence of an allelic variant which differs from the reference
- 30 sequence set forth in SEQ ID NO:1; and

- c) selecting the appropriate drug to administer to a patient who has an inflammatory disease or disorder based on the presence of an allelic variant which differs from the reference sequence set forth in SEQ ID NO:1, wherein the allelic variant comprises one or more nucleotide sequences selected from the group consisting of those set forth in
- 5 SEQ ID NO: 4, SEQ ID NO:5, and SEQ ID NO:6, or the complement thereof.

19. The method of claim 18, wherein the allelic variant further comprises one or more nucleotide sequences selected from the group consisting of SEQ ID NO: 7 and SEQ ID NO:8, or the complement thereof.

10

20. The method of claim 18 or 19, wherein the allelic variant further comprising at least one non-wild-type Sp1 binding site allele, or the complement thereof.

21. The method of claim 18, wherein the drug is a 5-LO inhibitor.

15

22. A method of identifying a patient who is a candidate for effective treatment with a 5-LO inhibitor comprising the steps of:

- a) obtaining a nucleic acid sample from the patient;
- b) determining the presence of an allelic variant which differs from the reference
- 20 sequence set forth in SEQ ID NO:1; and

c) identifying a patient who is a candidate for effective treatment with a 5-LO inhibitor based on the presence of an allelic variant which differs from the reference sequence set forth in SEQ ID NO:1, wherein the allelic variant comprises one or more nucleotide sequences selected from the group consisting of those set forth in SEQ ID NO: 4,

25 SEQ ID NO:5, and SEQ ID NO:6, or the complement thereof.

23. The method of claim 22, wherein the allelic variant further comprises one or more nucleotide sequences selected from the group consisting of SEQ ID NO: 7 and SEQ ID NO:8, or the complement thereof.

30

10071441.020702

24. The method of claim 22 or 23, wherein the allelic variant further comprising at least one non-wild-type Sp1 binding site allele, or the complement thereof.

25. The method of claim 22, wherein the patient has an inflammatory disease or disorder.

26. The method of claim 22, wherein the patient has asthma.

27. A method for determining the identity of an allelic variant of a 5-LO gene in a nucleic acid obtained from a patient, wherein the sample comprises a 5-LO gene sequence,

10 comprising contacting a sample nucleic acid from the patient with a probe or primer having a sequence which is complementary to a 5-LO gene sequence, wherein the probe or primer is selected from the group consisting of nucleic acids having a nucleotide sequence set forth in SEQ ID NO: 4, SEQ ID NO:5, or SEQ ID NO:6, or the complement thereof, and wherein the allelic variant comprises one or more nucleotide sequences selected from the group

15 consisting of those set forth in SEQ ID NO: 4, SEQ ID NO:5, and SEQ ID NO:6, or the complements thereof, thereby determining the identity of the allelic variant.

28. The method of claim 27, wherein determining the identity of the allelic variant comprises determining the identity of at least one nucleotide at any one of the nucleotide

20 residues selected from the group consisting of: residue 1000 of SEQ ID NO:1, any one of residues 472-477 of SEQ ID NO:1, and residue 559 of SEQ ID NO:1.

29. The method of claim 27, wherein determining the nucleotide content comprises sequencing the nucleotide sequence.

30. The method of claim 27, wherein determining the identity of the allelic variant comprises performing a restriction enzyme site analysis.

31. The method of claim 27, wherein determining the identity of the allelic variant is carried out by single-stranded conformation polymorphism.

32. The method of claim 27, wherein determining the identity of the allelic variant is carried out by allele specific hybridization.

5 33. The method of claim 27, wherein determining the identity of the allelic variant is carried out by primer specific extension.

34. The method of claim 27, wherein determining the identity of the allelic variant is carried out by an oligonucleotide ligation assay.

10

35. The method of claim 27, wherein the probe or primer comprises a nucleotide sequence from about 15 to about 30 nucleotides.

36. The method of claim 27, wherein the probe or primer is labeled.

15

10071411.020702